IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Andrew A. WOLFF, et al.

Title: SUSTAINED RELEASE RANOLAZINE FORMULATIONS

Patent. No.: 6,864,258

Issue Date: 3/8/2005

Examiner: Konata M. George

Art Unit: 1616

Confirmation Number: 7581

REQUEST FOR CERTIFICATE OF CORRECTION FOR PTO MISTAKE PURSUANT TO 37 C.F.R. § 1.322(a)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed, in duplicate, is a Certificate of Correction, Form PTO-1050, for United States Patent Number 6,864,258 issued March 8, 2005. The following Patent Office printing errors appear in the issued patent:

IN THE CLAIMS

IN THE CLAIMS

In Column 18, Claim 1, lines 40-42, please replace "a cardiovascular disease selected from arrhythmias, variant and exercise-induced angina, and myocardial infarction" with -- chronic angina --;

In Column 18, Claim 5, line 66, please replace "dosed" with -- doses --;

In Column 19, Claim 8, line 11, please delete the comma (,) after the word "acetate".

Applicants submit that the typographical errors in the claims noted above were previously amended in the Second Preliminary Amendment submitted to the United States Patent Office on September 15, 2003. Please find a copy of the relevant document attached herewith. Therefore, the typographical corrections made herein do not constitute new matter and correction thereof would not require reexamination.

Pursuant to 37 C.F.R. §1.322, Applicant requests that the enclosed Certificate of Correction be approved.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

Date March 13, 2008 By _____

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Attorney for Applicant
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MODIFIED PTO/SB/44 (04-05)
Approved for use through 04/30/2007. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO.	:	6,864,258
APPLICATION NO.	:	10/614,460
DATED	:	3/8/2005
INVENTOR(S)	:	Andrew A. WOLFF; Fiona BAKER; John Richard LANGRIDGE

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS

In Column 18, Claim 1, lines 40-42, please replace "a cardiovascular disease selected from arrhythmias, variant and exercise-induced angina, and myocardial infarction" with -- chronic angina --;

In Column 18, Claim 5, line 66, please replace "dosed" with -- doses --;

In Column 19, Claim 8, line 11, please delete the comma (,) after the word "acetate".

MAILING ADDRESS OF SENDER (Please do not use customer number below):

975 Page Mill Road
Palo Alto, California 94304-1125

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 98,164-A24)

In the Application of:	)	
	)	
Wolff	)	Examiner: Unknown
	)	
Serial No. 10/614,460	)	Group Art Unit: Unknown
	)	
Filed: July 7, 2003	)	
	)	
Title: Sustained Release Ranolazine Formulation	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

TRANSMITTAL LETTER

In regard to the above identified application:

1. We are transmitting herewith the attached:
   a. Second Preliminary Amendment
   e. Postcard

2. With respect to additional fees:
   a. Attached is a check in the amount of $ -0-

3. Please charge any additional fees or credit overpayment to Deposit Account No.13-2490. A duplicate copy of this sheet is enclosed.

4. CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1 hereinabove, are being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 11th of September, 2003.

By: _____
A. Blair Hughes
Reg. No. 32,901

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IN THE UNTIED STATES PATENT AND TRADEMARK OFFICE
(Case No. 98-164-A24)

In the Application of	)	
	)	
Wolff	)	
	)	Examiner: Unknown
Serial No. 10/614,460	)	
	)	
Filed: July 7, 2003	)	Group Art Unit: Unknown
	)	
Title: Sustained Release Ranolazine Formulations	)	

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SECOND PRELIMINARY AMENDMENT

Sir:

Please amend the claims as follows.

Amendments to the Claims are reflected in the listing of claims that begins on page 2 of this paper.

Remarks begin on page 6 of this paper.

IN THE CLAIMS

1. (currently amended) A method for treating a human patient suffering from ~~a cardiovascular disease selected from arrhythmias, variant and exercise-induced angina, and myocardial infarction~~ chronic angina by administering a sustained release pharmaceutical dosage form including at least 50% by weight ranolazine in no more than two tablets per dose to the human patient to maintain ranolazine plasma levels in the human patient of from about 550 to about 7500 ng base/mL for at least 24 hours wherein the dose is administered at a frequency selected from once, twice and three times over 24 hours.

2. (original) The method of claim 1 wherein the sustained release dosage form includes at least one pH dependent binder wherein the pH dependent binder inhibits the release of ranolazine from the sustained release dosage form when the sustained release dosage form is subjected to an aqueous environment having a pH of the stomach and wherein the pH dependent binder promotes the release of a therapeutic amount of ranolazine in an aqueous solution having a pH above about 4.5.

3. (original) The method of claim 2 wherein the pH dependent binder is partially neutralized.

4. (original) The method of claim 1 wherein the pharmaceutical dosage form is administered to the human patient at a frequency selected from once and twice over 24 hours.

5. (currently amended) The method of claim 1 wherein the pharmaceutical dosage form is administered to the human patient in two ~~dosed~~ doses over 24 hours wherein each dose consists of two tablets.

6. (original) The method of claim1 wherein the pharmaceutical dosage form includes between about 50% to about 95% by weight ranolazine.

7. (original) The method of claim 1 wherein the pharmaceutical dosage form includes from about 70% to about 80% by weight ranolazine.

8. (currently amended) The method of claim 2 wherein the pH dependent binder is selected from methacrylic acid copolymers, hydroxypropyl cellulose phthalate, hydroxypropyl methylcellulose phthalate, cellulose acetate phthalate, polyvinyl acetate, phthalate, polyvinylpyrrolidine phthalate, and mixtures thereof.

9. (original) The method of claim 2 wherein the pH dependent binder is a methacrylic acid copolymer.

10. (original) The method of claim 9 wherein the methacrylic acid copolymer is methacrylic acid copolymer Type C USP.

11. (original) The method of claim 2 wherein the pH dependent binder is from about 5 to about 12 wt% methacrylic acid copolymer Type C USP.

12. (original) The method of claim 1 wherein the pH dependent binder is about 10 wt% methacrylic acid copolymer Type C USP.

13. (original) The method of claim 1 wherein the pharmaceutical dosage form includes a pH-independent binder.

14. (original) The method of claim 13 wherein the pH-independent binder is selected from hydroxypropyl methylcellulose, hydroxypropyl cellulose, poly(meth)acrylate esters, polyvinylpyrrolidone, and mixtures thereof.

15. (original) The method of claim 13 wherein the pH-independent binder is hydroxypropyl methylcellulose.

16. (original) The method of claim 15 wherein the pharmaceutical dosage form includes from about 1 to about 3 wt% hydroxypropyl methylcellulose.

17. (original) The method of claim 15 wherein the pharmaceutical dosage form includes about 2 wt% hydroxypropyl methylcellulose.

18. (original) The method of claim 1 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 wherein the human patient plasma ranolazine level ranges from 1000-5000 ng base/mL.

19. (original) The method of claim 1 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 wherein the human patient plasma ranolazine level ranges from 1000-3800 ng base/mL.

20. (original) The method of claim 1 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 wherein the human patient plasma ranolazine level ranges from 550-5000 ng base/mL.

21. (original) The method claim of 1 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 wherein the human patient plasma ranolazine level ranges from 550-3800 ng base/mL.

22. (original) The method of claim 1 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 wherein the human patient plasma ranolazine level ranges from 1000-2800 ng base/mL.

23. (original) The method of claim 1 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 wherein the human patient plasma ranolazine level ranges from 1700-3900 ng base/mL.

24. (original) The method of claim 1 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 wherein the human patient plasma ranolazine level ranges from 550-2000 ng base/mL.

25. (original) The method of claim 23 wherein the dosage form includes from 650-850 mg ranolazine.

26. (original) The method of claim 24 wherein the dosage form includes from 900-1100 mg ranolazine.

27. (original) The method of claim 25 wherein the dosage form includes from 400-600 mg ranolazine.

28. (original) The method of claim 22 or 23 or 24 or 25 or 26 or 27 wherein the peak to trough human patient plasma ranolazine levels is less than 4:1 over a 24 hour period.

29. (original) The method of claim 23 or 24 or 25 or 26 or 27 wherein the peak to trough human patient plasma ranolazine levels is less than 3:1 over a 24 hour period.

30. (original) The method of claim 24 or 28 wherein the peak to trough human patient plasma ranolazine levels is less than 2:1 over a 24 hour period.

Claims 31-50 (cancelled)

REMARKS

Claims 1-30 are pending in the application. Claims 31-50 were cancelled from the application without prejudice in a Preliminary Amendment filed contemporaneously with the application.

Claim 1 has been amended to specify that the method is for treating a human patient suffering from chronic angina. Support for this amendment can be found, for example, in Example 4 (page 24, line 5).

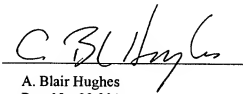
Claim 5 has been amended to correct a typographical error (dosed was amended to read doses).

Claim 8 has been amended to correct two typographical errors (spacing for hydroxypropyl cellulose in the 2nd line of the claim and removal of a comma between acetate and phthalate in the 3rd line of the claim).

No new matter has been added to the application by way of these amendments.

Respectfully Submitted,
McDonnell Boehnen Hulbert & Berghoff

Date: September 11, 2003

By: 

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